

HEMOPHILIA ADVISORY BOARD

Minutes of the December 1, 2008 Meeting

Members Present

Paul Brayshaw
Tracey Cleghorn
B. Gail Macik
Gita Massey
Craig Smith (speaker phone)

Staff

Jan Kuhn
Tamara Quarles

Members Absent

Sylvia Richendollar

Interested Parties

Becky Bowers-Lanier
Nancy Bullock
Rachel Cain
Janice Cole
Lauren Dunn
Ryan Faden
Mike Herbert
Terry Lamb
Dana Kuhn
Kate Lynch
Mindy Nolte
Kevin O'Connor
Sandi Qualley
Kim Stewart
Kelly Waters
Eric Werner

I. Introduction of members

The meeting was called to order at 10:10 a.m. A membership list was distributed for revision. Conflict of interest disclosure statements for board members were disseminated, and information on the related training was made available. Jan Kuhn noted that the Secretary of the Commonwealth's office is aware that two members' terms have expired, and the position of general public remains vacant. The office is actively seeking renewal or reappointment.

II. Minutes

As recommended by the Board at their December 3, 2007 meeting, the minutes of this meeting will be disseminated shortly after the meeting for review with a sunset date for comments. The minutes will be posted by 30 days from this meeting.

III. Annual Virginia Bleeding Disorders Program (VBDP) Update

Jan began the program report with a review of the agenda as the items related to the core functions of public health. She then discussed current program enrollment statistics, with comparisons to last year's report where significant. In fiscal year 2008, the program served 259 patients (2007: 270; 2006: 257). Most of the patients on the program have either severe or moderate Factor VIII Deficiency. The percentages by gender, diagnosis and clinic have remained similar to 2007. Jan noted that the Northern Virginia satellite of the Children's National Medical Center is now holding routine comprehensive hemophilia treatment center (HTC) clinics, staffed by Dr. Naomi Luban. They moved sites over the summer to the Falls Church office and have incorporated patients from Dr. Jay Greenberg's private practice into comprehensive care. Jan then presented a more detailed report on patients by insurance, identifying nine percent of the patients on Medicare and twenty-six percent with fee-for-service or managed Medicaid. Fifty-five percent have private insurance, and ten percent are uninsured. Fifteen patients used Pool of Funds (POF) in fiscal year 2008 with 67% uninsured, 11% capped and 22% having a pre-existing condition. The percentage of uninsured patients receiving POF has increased and was deferred to a discussion later in the meeting.

Jan then discussed the need for clarification of spend-down definition. The issue was raised, in part, by an appeal of the spend-down this year. Four issues were identified: 1) Should spend-down be paid in twelve equal payments? 2) What should be included in spend-down? 3) Does spend-down include outstanding bills or expenses in a given time? If so, what is that time frame? and 4) Should persons with variable incomes have spend-down reviewed monthly rather than yearly?

The Board agreed that the spend-down should be in twelve equal payments. Health insurance premiums paid by the patient or family for the patient could be included in spend-down. Medical bills incurred six months prior to enrollment or prior to the change of insurance status could be included in spend-down. Patients with variable incomes may have incomes may have the spend-down determined on a monthly basis.

Recommendations:

The Board approved the following modification to the Pool of Funds Guidelines under the area of "Financial Requirements":

Once the family has incurred or been billed for medical services equaling 5.0% of their gross annual income for medical bills of the patient(s), ~~during the twelve month period from the date of admission to the program~~, the Pool of Funds may be accessed for covered services. *Allowable medical expenses include doctor or dentist bills, hospital bills, medication bills, health insurance premiums paid by patient or family, and certain medical supplies. Medical expenses paid by Medicaid, Medicare or insurance do not apply to spend-down. Bills may be incurred during a twelve month period, beginning six months prior to the eligibility date of a newly enrolled or reenrolling patient. If a patient loses health care coverage during after annual enrollment, bills incurred six months prior to the loss of coverage may be included in spend-down.* Due to the extremely high cost of hemophilia medications, patients with inherited bleeding disorders may pay the annual medical spend-down in *twelve equal* monthly installments to the program coordinator. The spend-down must be fully paid by the end of the 12-month period from the annual recertification date.

IV. Virginia Department of Health (VDH): A Highlight of Priorities and Initiatives for 2008-2009

Eric Werner introduced Karen Remley, State Commissioner of Health. Karen discussed four priorities of VDH: 1) Safeguarding the Health of Children; 2) Improving Access to Care; 3) Ensuring Emergency Preparedness and Response; and 4) Serving as Responsible Stewards of Taxpayer Funds.

Karen discussed three VDH priorities regarding child health: Virginia Immunization Information system, Childhood Obesity, and Infant Mortality. The goal of the VA Immunization Information System is to develop an accessible, complete and accurate immunization record. With regard to childhood obesity, Karen discussed two new Virginia laws that were passed legislation passed in 2008 to enhance public school physical fitness requirements and to develop a data base of best practices regarding nutrition and physical education in schools. Reduction of the Infant Mortality Rate (IMR) is another priority for child health. In addition to strategies to reduce prematurity, VDH is targeting the reduction of IMR for children over 27 days.

Karen next discussed improving access to care through both the funding of indigent care-Certificate of Public Need condition and the Statewide Rural Health Plan. The latter is a 3-5 year strategic plan designed to strengthen the health care infrastructure in rural areas. She also discussed the high rating that Virginia has received in emergency preparedness and response in both outbreak investigation and containment and disaster relief. Finally, Karen discussed VDH's efforts to increase reimbursements for services that are billable to private insurers as one strategy to serve as responsible stewards of taxpayer funds.

Karen then addressed concerns about possible budget cuts to the VBDBP due to the statewide deficit. She noted that recommendations for budget cuts considered whether the program was mandated and whether the program was duplicative of other available services.

V. Patient Services Incorporated (PSI) Presentation

Mike Herbert from PSI presented their annual report. He discussed the number of clients served in the past year and presented trend data since 1996. He also discussed the cost avoidance to the state for patients who receive case management and premium assistance through PSI. He discussed the numbers of patients transitioning off of PSI assistance and the reasons for no longer needing PSI services. Additionally, Mike discussed new legislative efforts for funding.

Mike noted increased efforts by PSI and VBDBP to case manage patients by monthly conference calls between PSI, Virginia Commonwealth University (VCU) HTC and VBDBP staff. He also noted that PSI is now administering the Virginia State Pharmaceutical Assistance Program (SPAP). This has assisted the team in understanding options for patients on supplemental Anthem policies that might benefit from a Medicare Advantage Plan with or without assistance from SPAP.

Unfortunately, Mike noted that the recent economic downturn and increased demand for assistance has diminished opportunities to maintain in-kind additional funding support. He noted that PSI instituted several policy changes in July of 2008 that will be fully implemented in 2009 to address the financial limitations. These include instituting a waiting list for premium assistance, a five to seven percent share of cost for clients at or above 200% of FPL, an annual assistance capitation of \$11,000 per client and assistance limited to three consecutive years. The first two policies were implemented in July of 2008. The capitation will be implemented starting January 1, 2009 and the restrictions on length of time on service will begin July 1, 2009. Mike noted that PSI has offered modification of the final two policies for VBDP and is interested in working with them to meet the program needs.

VI. Program Budget

Jan presented an overview of the FY09 Virginia Bleeding Disorders Program (VBDP) budget with expenditures to date. She discussed trends in health insurance that are now being realized in the VBDP budget. These include significant increases in health insurance premiums and higher rates of uninsured Virginians, specifically those between 19 and 24 years of age.

Jan then presented data on use of Pool of Funds for the past three years and for the current fiscal year. Dramatic increases in utilization in this fiscal year and a dramatic rise in the number of young males with severe and moderate hemophilia who are uninsured. She noted that there is a two fold increase in the number of patients on POF from ages 19-25 years and a 2.5 fold increase in severe patients. She reiterated Mike's discussion of the changes in PSI policies, beginning in July of 2008 as a result of higher premiums, increased demands and limited donations. The resulting waiting list for PSI services has led to a larger number of patients eligible for POF services that are uninsured with no immediate ability to secure insurance or Medicaid/Medicare. At this time over 55% of the VBDP POF budget has been already spent in FY09.

Jan then summarized possible budget cuts by two broad categories: Reducing contracts or Reducing POF. Strategies to reduce contract costs included reducing the PSI contract, the administration contract or nursing contracts to HTCs. She noted that the HTCs have taken a budget cut in FY09 for both Maternal and Child Health Bureau funding and Centers for Disease Control and Prevention (CDC) funding. Eric asked if any centers in Virginia were participating in the 340 B Factor Dispensing Program. Jan reported that at least two centers have filed with the Office of Pharmacy Affairs, but no Virginia HTC has enrolled patients to date.

Then Jan summarized the strategies to reduce POF. These strategies are all based on stable compassionate use programs by manufacturers. Strategies included eliminating POF, instituting a waiting list, reducing POF and increasing PSI funding, restricting user type, reduce POF total cap or the cap for outpatient factor for home use.

Jan then discussed the strategies to date to transition patients off of PSI services. She thanked Lauren Dunn and Mike for their work in exploring Medicare Advantage options. She also noted that VBDP, Lauren and PSI are having monthly phone calls to help case manage patients.

Eric asked why the donations to PSI have declined, and Dana Kuhn responded that donations from factor home infusion companies have declined. He noted that many of the newer specialty pharmacies affiliated with insurance companies do make donations to non-profits; however, PSI does not fit the type of contributions that these foundations support. Paul asked if 340 B programs donate to PSI. Dana said that they do; however, there are not any active 340B programs in Virginia. Gail Macik mentioned that \$15,000 in factor concentrate for an adult was not much but hopefully enough to transition onto a compassionate use program.

Recommendation: The Board discussed the pros and cons of these options and recommended capping the POF outpatient factor for home use to \$15,000. Patients will be transitioned into this policy as new applications for compassionate use may take a few weeks. Full implementation should occur by January 15, 2009.

Jan reminded the HAB that the VBDP needs to review the full implementation of the PSI policies and ascertain the policies for the VBDP clients that they want to adopt. The policies to increase family participation and to institute a waiting list has already been instituted; however, specific policies for length of time on service and the amount of family participation has not been delineated.

Recommendation: The Board agreed to establish a subcommittee to make recommendations regarding the implementation of PSI policies by patients on the VBDP. Tracey Cleghorn and Paul Brayshaw agreed to be Board representatives on the subcommittee. Lauren Dunn agreed also to serve on the subcommittee as a HTC representative.

VII. Private Health Insurance Caps

Lauren Dunn presented an update of the discussion from the 2007 HAB meeting on health insurance caps. The Board asked for additional information about the percentage of patients enrolled in the VBDP who have a lifetime cap, the type of cap coverage (prescription, major medical or both), the average amount of the cap and the number of patients nearing their cap. Additionally the HAB was interested in what percentage of patients are covered by fully insured group, self insured group, or individual plans.

Lauren thanked Tamara Quarles and Jamie Leonard (VCU data manager) for their assistance with this effort. The data obtained thus far does not answer the type of coverage (fully vs. self-insured), but begins to answer some of these critical questions. She noted 135 of the 259 persons on the VBDP have insurance. Sixty-six percent of these patients do not have a cap. Of those who have a cap, twenty-one percent have a one million dollar cap.

Lauren also discussed with the HAB the status of federal legislation on insurance caps. HR 6528 / S 2706 (Health Insurance Coverage Protection Act) proposes to raise the minimum lifetime caps in private insurance plans to \$5 million for the first two years and \$10 million in years three and four, with an annual inflationary update thereafter. Lauren also listed the broad range of supporters, including the National Hemophilia Foundation and the Hemophilia Federation of America.

Paul shared some concerns that health insurance companies may offset their cost toward increased caps by raising copays, coinsurance, deductibles and premiums.

Recommendation:

The HAB agreed to write a letter to the patrons of the bills in support of HR 6528 and S 2706. Concerns about cost-shifting to the patient should be included in the letter of support.

VIII. National Hemophilia Foundation (VHF) Standards of Care

Kelly Waters from the Virginia Hemophilia Foundation presented the Standards of Services for Pharmacy Providers of Clotting Factor Concentrates for Home Use to Patients with Bleeding Disorders. This issue had been on the agenda for the HAB several years ago. The new standards have six basic components: 1) Pharmacy provider staff knowledge of clotting factor concentrates; 2) Clotting factor concentrates and ancillaries; 3) Processing of prescription orders; 4) Hours of operation and access to staff; 5) Delivery; and 6) Recordkeeping, Billing and Product Recall. Kelly noted that the Standards are guidelines and not enforced by any one group or agency. Jan also noted the State Pharmacy does not meet some of the guidelines such as par level of factor and hours of operation.

IX. Life Insurance and Inherited Bleeding Disorders

Jan noted that several patients and center social workers have brought the issue of access to life insurance for persons with inherited bleeding disorders to her attention and possible interest of the Board. Individual life insurance policies require personal and family medical history to rate individuals. These ratings influence whether coverage will be offered and the rate of the coverage. Many patients with inherited bleeding disorders are excluded from life insurance benefits or receive extremely high ratings. These high rating scales may also include patients with mild disease and no co morbidities.

Current studies on life expectancy or mortality rates provide limited information on patients without co-morbidities or for mild patients. Jan suggested that the Universal Data Set of statistics reported by HTC's to the CDC might be a source of data for this information. Eric discussed the concerns regarding the implications of labeling for mild diagnoses, especially for diseases such as mild von Willebrand Disease where diagnosis is not always clear. Paul shared his concerns about whether there would be enough longitudinal data to be statistically significant. Sandi Qualley shared that this was an issue of importance to her chapter members and supported further consideration. Gail noted that other endpoints may also be considered.

Recommendations:

The Board agreed to request the CDC to explore whether the UDC or other HTC data might delineate the mortality rate or possible life expectancy for patients with inherited bleeding disorders who either have mild disease or do not have co-morbidities such as hepatitis or HIV infection.

X. Von Willebrand Disease (vWD) Outreach to Adolescent Females in Family Planning Clinic

Jan presented a new initiative that the VBDP in conjunction with the VCU HTC will be undertaking with local health district family planning (FP) clinics. The program goal is to provide education and outreach regarding vWD to local health department clinics in the Richmond area. Jan noted that the project has been funded by a Children's Miracle Network minigrant through VCU, thus the reason for the location of outreach. The objectives of the grant are to educate family planning clinic health care providers on von Willebrand Disease through their existing web-based curriculum and continuing education programs. The funding will provide for the purchase of brochures and travel to clinics or educational sites for training. To that end, the initiative asks the HAB to establish a subcommittee to guide its work, especially in terms of the referral network issues that may arise if youth at risk for vWD are identified by local FP clinics. Jan has spoken with the VDH director of family planning to obtain their insight into the project.

Craig Smith added that he would be happy to help local health districts understand the importance of this initiative. He added that this would have a low impact to staff demands given the limited number of referrals likely. Eric added that the education needs to include the differential diagnoses for menorrhagia and screening for anemia. He agreed to be a speaker for some of the continuing education opportunities. Becky Bowers asked if other organizations like Planned Parenthood could participate in the training. Mindy Nolte, Kim Stewart and Kate Lynch agreed to be on the subcommittee.

Recommendation:

The Board recommended the establishment of a subcommittee to guide the work of this project.

XI. NHF/YMCA Physical Activity Initiative in Collaboration with the CDC

Jan provided the incidence of overweight and obesity in the bleeding disorders community, as identified by the CDC. She then discussed an initiative of the VHF to enable individuals and their families with bleeding disorders to exercise and maintain a healthy weight to protect their joints. VHF is one of six pilot sites to develop the program in conjunction with the Greater Richmond YMCA. VCU HTC staff has provided education to the YMCA wellness directors. Jan thanked Kelly at VHF for their outstanding work on this grant. Gail asked if patients outside of Richmond could benefit. Kelly noted that the grant targets the Richmond area; however she noted that the VHF Board is open to considering assistance for other families interested in the program. Eric commended Kelly on her work. He did note that, in considering childhood obesity, we also need to focus on very young children that might not be directly served by this grant.

XII. Emergency Preparedness for the Bleeding Disorders Community

Jan presented an overview of the work to-date undertaken by the American Thrombosis and Hemostasis Network (ATHN) to address national disaster preparedness called ATHN Ready. She thanked Lauren and Eric for their work on ATHN subcommittees.

ATHN Ready includes several initiatives to address disaster preparedness. These include a centralized data base for secure access by HTC's to patient information, a standardized, password protected, portable medical report on flash drive for individual use, a tool kit for HTC preparations and a national awareness campaign.

XIII. Transition from Pediatric to Adult Care

Jan reviewed the work in 2007-2008 of the Transition Subcommittee and various HTC's. She noted that an abstract describing their efforts was accepted by the American Academy of Pediatrics for a poster session at the 2009 annual meeting. Jan asked if the HAB wanted the subcommittee to continue.

Nancy encouraged the teams to consider involving adolescents in planning. Kate and Lauren noted the barriers in engaging youth in planning and participation in such activities. Kelly and Sandi encouraged involvement of local chapters in transition efforts; however, Kelly noted that the VHF attempts to address these needs have not been attended by youth in greatest need of transition education. Gail noted that there are still outstanding issues regarding transition to adult clinics, including strategies to increase the independence of young adults in their care and considerations of employment opportunities. Eric noted that transition is seen as a critical issue for many national and state organizations including AAP, VDH, and ASH and that the subcommittee should continue its work.

Recommendations

The Board recommended that a Transition Subcommittee be continued.

XIV. Bylaws

Jan disseminated draft bylaws for the Board's review. She will make some modifications and distribute to the Board for approval.

XV. Public Comment

No public comment was noted. The meeting was convened at 2:20 pm.